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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/871,125

Applicant(s)

PARIZA ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 9,15-17 and 19-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,10-14 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election with traverse of the invention of Group I, claims 1 (in part) and 9 in Paper No. 6, received March 5, 2002 is acknowledged. The traversal is on the ground(s) that the inventions of Group I-II and III-IV and V-VI are related. This is not found persuasive because the inventions encompassed by the claims in the instant invention are patentably distinct invention. Separate classifications among the invention show that each distinct subject has attained recognition in the art as a separate subject for invention effort, and also a separate field of search (See MPEP 808.02). The inventions herein function differently. Note that the search fields for materially different methods of use employing a composition containing the same ingredients are diverse. The present methods relate to a separate field of medical technology e.g., controlling body fat, reducing triacylceride, and inhibiting lipoprotein lipase activity; each having a separate field of search. In addition, the search fields for method; each employing different compositions, are diverse. Each composition contains different active ingredients classified in different classifications, which are recognized as separate fields of art. The search is not limited to patent files. Therefore, the search for the methods encompassed by the claims presents an undue burden to the Office.

Moreover, Applicant submits that it is improper for Examiner to assert in Group II that control of body fat in this method as amended is achieved by administration of CLA. This remark has been considered, but is not found persuasive. The restriction requirement issued in the previous Office action mailed December 28, 2001 is based on

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the claims filed as then. Claim 10 clearly recites the method of controlling body fat by administering CLA. This is not an assertion by the examiner.

Applicant's election with traverse of the species, Nordihydroguaiaretic acid (NDGA) and the animal specie, mouse, in Paper No. 6, received March 5, 2002 is acknowledged. The traversal is on the ground(s) that all the compounds recited herein have the same function and thus, undue burden for search is not present. This is not found persuasive. The compounds herein are patentably distinct compounds, even though they may have similar functions. The search fields for different compounds would be different. For example, lisinopril and captopril are both ACE inhibitors; however, both compounds are patentably distinct. The search for all compounds encompassed by the claims herein present an undue burden to the Office.

Upon reconsideration, claims <sup>10-14, 17-19</sup> 10-19 will be included in the invention of Group I, a method of controlling body fat in an animal by administering a lipoxigenase inhibitor.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-16, 20-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 9, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 1-8, 10-14, and 18 are examined on the merits herein to the extent they read on the elected invention and species.

***Claim Rejections - 35 USC § 103***

*claim 17.*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8,10-14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khandwala et al. (US Patent 5,827,898 from the Information Disclosure Statement received October 5, 2001), Park et al. (Lipids, 1999; 34(3): 235-241 from the Information Disclosure Statement received October 5, 2001).

Khandwala et al. teaches NDGA is known to be useful in reducing cholesterol and triglyceride level (note: reducing fat in the body)(See particularly col. 3, line 23-35). Khandwala et al. also teaches 350mg/kg of NDGA daily is useful in reducing body weight in mice (See col. 11, line 34 - col. 15; particularly Table 12).

Park et al. teaches *trans*-10,*cis*-12-conjugated linoleic acid is known in reducing body fat in mice (See particularly the abstract). Park et al. also teaches the amount of *trans*-10,*cis*-12-conjugated linoleic acid in the mice diet is around 0.25% (See particularly page 237, col. 1, fourth paragraph).

The references do not expressly teach the two agents are used together in the method of controlling body fat. The references do not expressly teach the amount of NDGA employed herein.

It would have been obvious to one skill in the art when the invention was made to employ NDGA and *trans*-10,*cis*-12-conjugated linoleic acid in the herein claimed amount in a method of controlling body fat.

One of ordinary skill in the art would have been motivated to employ NDGA and *trans*-10,*cis*-12-conjugated linoleic acid in the herein claimed amount in a method of controlling body fat because both NDGA and *trans*-10,*cis*-12-conjugated linoleic acid are known to be useful for controlling body fat (reducing body fat). Therefore, combining two agents which are known to be useful to reducing body fat individually into a method useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. In addition, the optimization of therapeutic effect parameters (dosage range, dosing regimens) is obvious, as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
May 20, 2002

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200